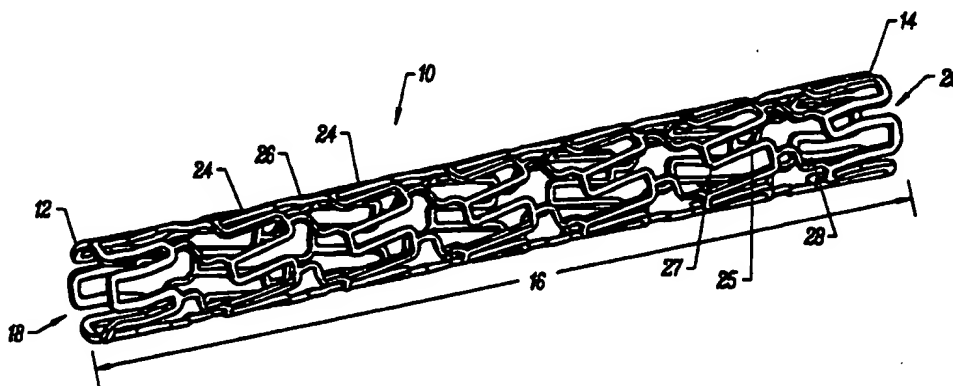




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(54) Title: INTRAVASCULAR STENT WITH NON-PARALLEL SLOTS



(57) Abstract

A stent in a non-expanded state includes a first expansion column having a plurality of first expansion column slots that are formed of a plurality of first expansion struts. Substantially each first expansion column slot has a longitudinal axis. A second expansion column has a plurality of second expansion column slots that are formed of a plurality of second expansion struts. Substantially each second expansion column strut has a longitudinal axis. A first connecting strut column is formed of a plurality of first connecting struts. The first connecting strut column couples the first expansion column to the second expansion column. The first expansion column, second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis. The longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure.

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INTRAVASCULAR STENT WITH NON-PARALLEL SLOTS**BACKGROUND OF THE INVENTION****5 Field of the Invention:**

This invention relates to intravascular stents, and more particularly to an intravascular stent which provides easy introduction through tortuous sections of vessels.

10 Description of the Related Art:

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. In the early 1980's, angioplasty first became available for clinical practice in the coronary artery, and has since proven an effective alternative to conventional
15 bypass graft surgery. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational arthroectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis
20 following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational arthroectomy. Intravascular stenting, however, noticeably reduces the restenosis
25 rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

The intravascular stent functions as scaffolding for the lumen of a vessel.
30 The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel; a

common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments include drug therapy and other methods mentioned previously.

Another benefit of vessel stenting is the potential reduction of emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases for treating impending closure of a vessel during angioplasty. Stenting can also control and stabilize an unstable local intimal tear of a vessel caused by normal conduct during an angioplasty procedure. In some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with a stent implant.

Early in its development, the practice of stenting, especially in coronary arteries, had serious anticoagulation problems. However, anticoagulation techniques have since been developed and are becoming simpler and more effective. Better and easier to use regimens are continuously being introduced, including simple outpatient anticoagulation treatments, resulting in reduced hospital stays for stent patients.

An example of a conventional stent patent is US 5,102,417 (hereafter the Palmaz Patent). The stent described in the Palmaz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

The unexpanded tubular members of the Palmaz Patent are overly rigid so that practical application is limited to short lengths. Even with implementation of the multilink design with flexible connector members connecting a series of tubular members, longer stents can not navigate tortuous blood vessels. Furthermore, the rigidity of the unexpanded stent increases the risk of damaging vessels during insertion. Foreshortening of the stent during

insertion complicates accurate placement of the stent and reduces the area that can be covered by the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapered expanded stent, and no method of reenforcement of stent ends or other regions is provided for.

Another example of a conventional stent patent is WO 96/03092, the Brun patent. The stent described in the Brun patent is formed of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns run perpendicular to the first meander patterns, along the axis of the tube.

Adjacent first meander patterns are connected by second meander patterns to form a generally uniform distributed pattern. The symmetrical arrangement with first and second meander patterns having sharp right angled bends allows for catching and snagging on the vessel wall during delivery. Furthermore, the large convolutions in the second meander pattern are not fully straightened out during expansion reducing rigidity and structural strength of the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapering stent design, and no method of reenforcement of stent ends or other regions is provided for.

These and other conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) lack of structural strength, radial and axial lateral, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

There is a need for a stent with sufficient longitudinal flexibility in the unexpanded state to allow for navigation through tortuous vessels. There is a further need for a stent that is structurally strong in the unexpanded state such that risk of damage or distortion during delivery is minimal. A further need

exists for a stent that maintains substantially the same longitudinal length during expansion to allow greater coverage at the target site and simplify proper placement of the stent. Yet a further need exists for a stent design with sufficient longitudinal flexibility that long stents of up to 100 mm can be safely delivered through tortuous vessels. There is a need for a stent that is configured to expand to variable diameters along its length, such that a taper can be achieved in the expanded stent to match the natural taper of the target vessel. A need exists for a stent which, (i) can be crimped tightly on the expansion balloon while maintaining a low profile and flexibility, (ii) has a smooth surface modulation when crimped over a delivery balloon, to prevent catching and snagging of the stent on the vessel wall during delivery, (iii) with reenforcement rings on the ends or middle or both to keep the ends of the stent securely positioned against the vessel walls of the target blood vessel or (iv) is flexible in a non-expanded state and becomes rigid when expanded.

SUMMARY OF THE INVENTION

Accordingly an object of the present invention is to provide a scaffold for an interior lumen of a vessel.

Another object of the invention is to provide a stent which prevents recoil of the vessel following angioplasty.

A further object of the invention is to provide a stent that maintains a larger vessel lumen compared to the results obtained only with balloon angioplasty.

Yet another object of the invention is to provide a stent that reduces foreshortening of a stent length when expanded.

Another object of the invention is to provide a stent with increased flexibility when delivered to a selected site in a vessel.

A further object of the invention is to provide a stent with a low profile when crimped over a delivery balloon of a stent assembly.

Yet a further object of the invention is to provide a stent with reduce tuliping of the stent struts during delivery through the body lumen.

Another object of the invention is to provide a chain mesh stent that reduces vessel "hang up" in a tortuous vessel or a vessel with curvature.

5 These and other objects of the invention are achieved in a stent in a non-expanded state. A first expansion column has a plurality of first expansion column slots that are formed of a plurality of first expansion struts. Substantially each first column expansion slot has a longitudinal axis. A second expansion column has a plurality of second expansion column slots that are formed of a plurality of second expansion struts. Substantially each second expansion column strut has a longitudinal axis. A first connecting strut column is formed of a plurality of first connecting struts. The first connecting strut column couples the first expansion column to the second expansion column. The first expansion column, second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis. The longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure.

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 In another embodiment, the slotted stent in the non-expanded state includes a first expansion column with a plurality of first expansion column slots that are formed of a plurality of first expansion struts. Substantially each first expansion column slot has a longitudinal axis. A second expansion column has a plurality of second expansion column slots that are formed of a plurality of second expansion struts. Substantially each second expansion slot has a longitudinal axis. A first connecting strut column is formed of a plurality of first connecting struts. The first connecting strut column couples the first expansion column to the second expansion column. The first expansion column, second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis and a plurality of geometric cells. At least a portion of the plurality of geometric cells are asymmetrical. The longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure.

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30 In another embodiment, a stent assembly includes a balloon and an expandable stent positioned at an exterior of the balloon. The stent has a first

expansion column with a plurality of first expansion column slots that are formed of a plurality of first expansion column struts. The first expansion column slots have a longitudinal axis. A second expansion column includes a plurality of second expansion column slots that are formed of a plurality of second expansion struts. The second expansion column slots have a longitudinal axis. A first connecting strut column is formed of a plurality of first connecting struts. The first connecting strut column couples the first expansion column to the second expansion column. The first expansion column, second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis that is non-parallel to the longitudinal axis of the first expansion column slots.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an isometric view of one embodiment of a stent in an unexpanded state with stent slots that are non-parallel to a longitudinal axis of the stent.

Figure 2 is an isometric side elevation view of the stent of Figure 1.

Figure 3 is a two-dimensional, lay-out view of the stent of Figures 1 and 2, with the non-parallel stent slots and the connecting struts of each connecting strut column extending substantially in the same direction.

Figure 4 is a magnified view of Figure 3.

Figure 5 is another embodiment of a stent in two-dimensional, lay-out view of an unexpanded stent with slots that are non-parallel to the longitudinal axis of the stent, and the connecting struts of a first connecting strut column extend substantially in one direction while the connecting struts of an second adjacent connecting strut column extend in a different direction, and each direction of the first and second connecting struts are non-parallel to the longitudinal axis of the stent.

Figure 6 is a magnified view of Figure 5.

Figure 7 is a two-dimensional, lay-out view of another embodiment of an unexpanded stent with slots that are non-parallel to the longitudinal axis of the stent, the stent includes stair-step connecting struts with sections that are substantially parallel to the longitudinal axis of the stent.

5 Figure 8 is a magnified view of Figure 7.

Figure 9 is a two-dimensional, lay-out view of another embodiment of an unexpanded stent with slots that are non-parallel to the longitudinal axis of the stent; the slots of a first expansion column are non-parallel to the slots of a second expansion column, the connecting struts of a first connecting strut column extend substantially in one direction while the connecting struts of an second adjacent connecting strut column extend in a different direction, and of the first and second connecting struts are non-parallel to the longitudinal axis of the stent.

Figure 10 is a magnified view of Figure 9.

15 Figure 11 is a two-dimensional, lay-out view of yet another embodiment of an unexpanded stent with slots that are non-parallel to the longitudinal axis of the stent; the slots of a first expansion column are non-parallel to the slots of a second expansion column, sections of the connecting struts are parallel to the longitudinal axis of the stent.

20 Figure 12 is a magnified view of Figure 11.

Figure 13 is a two-dimensional, lay-out view of an unexpanded stent where the slots of a first expansion column are parallel to the slots of a third expansion column but are not parallel to the slots of a second expansion column.

25 Figure 14 is a two-dimensional, lay-out view of an unexpanded stent where the slots of the second expansion column are formed of non-parallel expansion strut pairs.

Figure 15 is a perspective of a stent delivery system.

DETAILED DESCRIPTION

30 A first embodiment of the present invention is shown in Figures 1 through 4. An elongated hollow tubular stent 10 is a single prosthesis in an

unexpanded state. A proximal end 12 and a distal end 14 define a longitudinal length 16 of stent 10. The longitudinal length 16 of the stent 10 can be as long as 100 mm or longer. A proximal opening 18 and a distal opening 20 connect to an inner lumen 22 of stent 10. Stent 10 can be a single piece, without any seams or welding joints or may include multiple pieces. In the expanded state, the internal diameter of stent 10 is variably enlarged without substantially fore-shortening of the length of stent 10.

Stent 10 made in proper size and scale can be used for a variety of vascular and non-vascular lumens, as well as hollow body organs. Some specific body sites include coronary vessels, coronary bypass grafts, carotid arteries, renal arteries, peripheral vessels, bile ducts, the esophagus, the urethra, the aorta and the like.

Stent 10 is constructed of two to fifty or more expansion columns 24 linked together by interspersed connecting strut columns 26. The first column on the proximal end 12 and the last column on the distal end 14 of stent 10 are modified expansion columns 24.

Each expansion column 24 is formed of a series of expansion struts 25, and joining struts 27. Expansion struts 25 are thin elongated members. When an outward external force is applied to stent 10 from the inside by an expansion balloon or other means, expansion struts 25 are reoriented such that they extend in a more circumferential direction, i.e along the surface of stent 10. Reorientation of expansion struts 25 causes stent 10 to have an expanded circumference and diameter.

Expansion struts 25 and joining struts 27 form a plurality of expansion strut pairs 30 which define an expansion column slot 32. Expansion strut pairs 30 have a closed end 34 and an open end 36. Connecting struts 28 join together expansion struts 25 of adjacent expansion strut pairs 30, such that expansion struts 25 are joined alternately at their proximal and distal ends to adjacent expansion struts 25 to form expansion columns 24.

As illustrated more fully in Figures 2 and 4, a first expansion column 24' has a plurality of first expansion column slots 32' that are formed of a plurality of

first expansion strut pairs 30'. Substantially each first expansion column slot 32' has a longitudinal axis 42'. A second expansion column 24" has a plurality of second expansion column slots 32" that are formed of a plurality of second expansion strut pairs 30". Substantially each second expansion column slot 32" has a longitudinal axis 42". A first connecting strut column 26' couples the first expansion column 24' to the second expansion column 24". The width of adjacent first expansion column slots 32' are different, and the width of adjacent second expansion column slots 32" are also different. It will be appreciated that in other embodiments, the width and area of first expansion column slots 32' can be the same as second expansion column slots 32"; and adjacent first column expansion slots 32' can have the same width, as can the widths of adjacent second column expansion slots 32".

First expansion column 24', second expansion column 24" and first connecting strut column 26' form a first tubular structure 44' with a longitudinal axis 46'. Longitudinal axis 42' of first expansion column slots 32' is non-parallel to the longitudinal axis 46' of first tubular structure 44'. Second expansion column 24", second connecting strut column 26" and third expansion column 24" form a second tubular structure 44" with a longitudinal axis 46" that is substantially the same as longitudinal axis 46'.

Connecting struts 28' of first connecting strut column 26' have a longitudinal axis 50' that is substantially parallel to a longitudinal axis 50" of connecting struts 28" of second connecting strut column 26". Connecting struts 28' and 28" extend generally in the same direction and have a "stair-step" geometric configuration. Each connecting strut 28' and 28" has a proximal portion 52' and 52", distal portion 54' and 54" and an intermediate portion 56' and 56", respectively. In the embodiment of Figures 1 through 4, proximal portion 52' is coupled to a non-corner (intermediate section) of an expansion strut pair 30' of first expansion column 24', and a distal portion 54' is coupled to a corner section of an expansion strut pair 30" of second expansion column 24".

Connecting struts 28' and 28" include a plurality of angled junctions 58' and 58" which increase stent 10 introduction flexibility through the body lumen.

In the expanded state of stent 10, angled junctions 58' and 58" become substantially straightened out and reduce stent fore-shortening.

It will be appreciated that in other embodiments, only a portion of the adjacent connecting struts 28' or 28" include angled junctions 58' and 58", respectively.

Figure 3 is a scale drawing of a 16 mm stent with a circumference of 0.207 inches and particularly sized for coronary applications.

Stent 10 is ideally suited for application in coronary vessels although versatility in stent 10 design allows for applications in non-coronary vessels, the aorta, and nonvascular tubular body organs.

Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent 10 with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents 10 for coronary application; for example, small vessels stents for use in vessels with diameters from 2.5 mm to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm to 5.0 mm. Thus, both small vessels and large vessels when treated with the appropriate sized stent will contain stents 10 of similar idealized metal fraction.

Stent 10 can be made using a CAM-driven laser cutting system to cut the stent pattern from a stainless steel tube. The rough-cut stent 10 is preferably electro-polished to remove surface imperfections and sharp edges. Flat sheets of suitable metal can be cut with the stent portion and rolled into a tubular shape and welded. Other methods of fabricating stent 10 can also be used such as EDM, photo-electric etching technology, or other methods. Any suitable material can be used for stent 10 including other metals and polymers so long as they provide the essential structural strength, flexibility, biocompatibility and expandability.

Stent 10 is typically at least partially plated with a radiopaque metal, such as gold, platinum, tantalum or other suitable metal, and radiopaque mark under fluoroscopy. It is preferred to plate only both ends of the stent 10 by localized plating. However, the entire stent 10 or other regions can also be plated. When plating both ends, one to three or more expansion columns 24 on each end of stent 10 are plated to mark the ends of the stent so they can be identified under fluoroscopy during the stenting procedure. By plating stent 10 only at the ends, interference of the radiopaque plating material with performance characteristics or surface modulation of the stent frame is minimized. Additionally the amount of plating material required is reduced, lowering the material cost of the plating metal, such as gold.

After plating, stent 10 is cleaned, typically with detergent, saline and ultrasonic means that are well-known in the art. Stents 10 are then inspected for quality control, assembled with the delivery balloon catheter, and properly packaged, labeled, and sterilized.

Stent 10 can be modified for larger vessels such as renal arteries, the aorta, as well as any tubular body structure such as urethra, and the bile duct, as well as any other body lumens.

First expansion column 24', second expansion column 24" and first connecting strut column 26' form first tubular structure 44' which is made of a plurality of asymmetric cells 60'. Second expansion column 24", third expansion column 24''' and second connecting strut column 26" form second tubular structure 44" which is also made of a plurality of asymmetric cells 60". Cells 60' and 60" have approximately the same area. A cell 60' in first tubular structure 44' is laterally offset from a corresponding adjacent cell 60" in second tubular structure 44".

Another embodiment of stent 10 is illustrated in Figures 5 and 6. In this embodiment, connecting struts 28' in first connecting strut column 26' extend in an upward direction 62' while connecting struts 28" in adjacent second connecting strut column 26" extend in a downward direction 62". In this embodiment, there is more balanced flexibility during the delivery phase of stent

10 to the desired site. By arranging the axes 62' and 62" of connecting struts 28' and 28" in an alternating and generally opposing direction, any potential of axial warping of the stent 10 is prevented. The expansion strut pairs 30' and 30" are parallel to each other. The axes 42' and 42" of expansion column slots 32' and 32" are also parallel to each other, but they are nonparallel to the longitudinal axes 46' and 46" of stent 10. In the embodiment illustrated in Figures 5 and 6, cells 60' and 60" are asymmetrical.

In the embodiment illustrated in Figures 7 and 8, proximal portion 52' of connecting strut 28' is coupled to a corner of an expansion strut pair 30' of first expansion column 24', a distal portion 54' of connecting strut 28' is coupled to a corner section of an expansion strut pair 30" of second expansion column 24"; proximal portion 52" of connecting strut 28" is coupled to a corner of an expansion strut pair 30" of second expansion column 24", and a distal portion 54" is coupled to a corner section of an expansion strut pair 30". Connecting struts 28' and 28" have one stair-step. Proximal sections 52' and 52", and distal sections 54' and 54" are substantially parallel to longitudinal axes 46' and 46", respectively. This embodiment is an alternative in connection strut configuration.

Referring now to the embodiment of Figures 9 and 10, longitudinal axis 42' of first expansion column slot 32' is non-parallel to longitudinal axis 42" of slot 32" but is parallel to longitudinal axis 42'" of slot 32". Proximal portion 52' of connecting strut 28' is coupled to a non-corner of an expansion strut pair 30' of first expansion column 24' and distal portion 54' of connecting strut 28' is coupled to a corner section of an expansion strut pair 30" of second expansion column 24". Connecting struts 28' in first connecting strut column 26' extend in a downward direction 62' while connecting struts 28" in adjacent second connecting strut column 26" extend in an upward direction 62". Cells 60' and 60" have asymmetrical geometric configuration. The axes 42' and 42" of slots 32' and 32" are non-parallel to each other, and they are non-parallel to the axes 46' and 46" of stent 10. The expansion strut pairs 30' and 30" have two elongated struts that are parallel to each other.

In the embodiment of Figures 11 and 12, longitudinal axis 42' of first expansion column slot 32' is non-parallel to longitudinal axis 42" of slot 32". The expansion strut pairs 30' and 30" have elongated paralleling struts forming the slots 32' and 32". The axes 42' and 42" of slots 32' and 32" are non-parallel to the longitudinal axis 46' and 46" of stent 10. Cells 60' and 60" are symmetrical. Connecting struts 28' and 28" have a symmetrical "saddle" geometric shape with five sections. This symmetrical "saddle" shape of connective struts 28' and 28" provides uniform flexibility in the "north and south" directions perpendicular to the longitudinal axes 46' and 46" of stent 10. When stent 10 is in an expanded state, the saddle straightens out and thus reduces foreshortening.

Figure 13 illustrates an embodiment of stent 10 where longitudinal axis 42' is non-parallel to the longitudinal axis 46' of the first tubular structure 44'. Longitudinal axis 42" is non-parallel to the longitudinal axis 46", and the longitudinal axis 42' is non-parallel to the longitudinal axis 42".

First tubular structure 44' is formed of first closed cells 60' and second tubular structure is formed of second closed cells 60" which are asymmetrical. First closed cells 60' are non-mirror images of second closed cells 60". First and second connecting struts 28' and 28" each have a stair-step configuration.

Figure 14 illustrates another embodiment of stent 10 where longitudinal axis 42' is non-parallel to longitudinal axis 46'. Longitudinal axis 42' is non-parallel to longitudinal axis 46". First expansion column strut pairs 30' are parallel, second expansion column strut pairs 30" are non-parallel and third expansion column strut pairs 30" are parallel. First and second closed cells 60' and 60" are asymmetric cells. First closed cells 60' have different geometric shapes than second closed cells 60".

In the embodiments of the present invention, when stent 10 is expanded, expansion columns 24' and 24" become circumferentially stretched, enlarging the space between connecting struts 28' and 28". The interlinking of expansion columns 24' and 24" by connecting struts 28' that have been straightened through the expansion process provides stent 10 a high radial support strength. When

expanded, the entire stent 10 is unitized into a continuous chain mesh of stretched expansion columns 24', 24", 24"', and so on with connecting strut columns 26', 26" and so on, forming interlocking cells 60', 60" and continuing thereafter, which resists collapse both axially and radially. When stent 10 is expanded it has increased rigidity and fatigue tolerance.

In addition, efficient bending and straightening of connecting struts 28 and the like at angled junctions 58 allows increased stent 10 longitudinal flexibility during delivery phase. For stent 10 to bend longitudinally, at least some of connecting struts 28 are forced to bend in their tangent plane. The tangent plane of a specific connecting strut 28 refers to the plane substantially tangent to the cylindrical surface of the stent at that connecting strut 28. Angled junctions 58 provide connecting struts 28 a flexible joint about which to more easily bend increasing longitudinal flexibility of the stent.

In one embodiment, when fully expanded, stent 10 has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength, fatigue tolerance and fore shortening.

The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When stent 10 is optimally crimped over the delivery balloon, the surface of crimped stent 10 is smooth allowing for no snagging of stent struts during either forward or backward movement through a vessel or other body lumen.

Along with the use of a tapered diameter stent 10, a matching tapered balloon catheter would ideally be made for delivery and deployment of tapered diameter stent 10. The method of using a tapered matching balloon catheter with a tapered diameter stent is within the scope of the present invention. Furthermore, the tapered balloon could be curved lengthwise to match the tapered diameter stents within the scope of the present invention.

Using a tapered balloon to expand a non-tapered stent 10 will also achieve a tapered expanded stent 10. However, since no metal is removed from

stent 10, stent 10 is tapered as a result of incomplete expansion. Stent 10 will therefore have increased metal fraction at the tapered end resulting in increased risk of acute thrombosis. Metal fraction is the proportion of the surface of the expanded stent 10 covered by the stent strut material. Shortening expansion
5 struts 25 provides a tapered expanded stent 10 with substantially constant metal fraction along its length.

The stent can be marketed as stand alone or as a pre-mounted delivery balloon catheter assembly as shown in Figure 15. Stent 10 is crimped over a folded balloon 64 at the distal end 66 of a delivery balloon catheter assembly 68.
10 The assembly 68 includes a proximal end adapter 70, a catheter shaft 72, a balloon channel 74, a guidewire channel 76, a balloon 64, and a guidewire 78. Balloon 64 can be tapered in an expanded state, be curved from a proximal end to a distal end in the expanded state. Additionally stent 10 can be non-tapered or tapered in the expanded state.

15 Typically the guidewire 78 is inserted into the vein or artery and advanced to the target site. The catheter shaft 72 is then forwarded over the guidewire 78 to position the stent 10 and balloon 64 into position at the target site. Once in position the balloon 64 is inflated through the balloon channel 74 to expand the stent 10 from a crimped to an expanded state. In the expanded
20 state, the stent 10 provides the desired scaffolding support to the vessel. Once the stent 10 has been expanded, the balloon 64 is deflated and the catheter shaft 72, balloon 64, and guidewire 78 are withdrawn from the patient.

The stent of the present invention can be made as short as less than 10 mm in length or as long as 100 mm or more. If long stents are to be used,
25 however, matching length delivery catheter balloons will typically be needed to expand the stents into their deployed positions. Long stents, depending on the target vessel, may require curved long balloons for deployment. Curved balloons which match the natural curve of a blood vessel reduce stress on the blood vessel during stent deployment. This is especially important in many
30 coronary applications which involve stenting in curved coronary vessels. The use of such curved balloons is within the scope of the present invention.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A stent in a non-expanded state, comprising:

5 a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion struts, the first expansion column slots having a longitudinal axis;

a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion struts, the second expansion column slots having a longitudinal axis; and

10 a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis, and the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure.

2. The stent of claim 1, wherein the longitudinal axis of the second expansion slots is non-parallel to the longitudinal axis of the first tubular structure.

20 3. The stent of claim 1, wherein the longitudinal axis of the slots in the first expansion column is parallel to the longitudinal axis of the slots in the second expansion column.

25 4. The stent of claim 1, wherein at least one first connecting strut connects the first expansion column to the second expansion column.

30 5. The stent of claim 1, wherein a width of a first expansion column slot of the first expansion column is different from a width of a second adjacent expansion column slot of the first expansion column.

6. The stent of claim 1, wherein a width of a first expansion column slot of the first expansion column has a same width of a second adjacent expansion column slot of the first expansion column.

5 7. The stent of claim 1, wherein a width of each first expansion column slot is the same as a width of each second expansion column slot.

8. The stent of claim 1, wherein a width of each first expansion column slot is different from a width of each second expansion column slot.

10 9. The stent of claim 1, wherein the longitudinal axis of the first expansion column slots is parallel to the longitudinal axis of the second expansion column slots.

15 10. The stent of claim 1, wherein the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the second expansion column slots.

20 11. The stent of claim 1, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is non-parallel to the longitudinal axis of the first tubular structure.

25 12. The stent of claim 1, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is parallel to the longitudinal axis of the first tubular structure.

30 13. A slotted stent in a non-expanded state, comprising:
a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion struts, the first expansion column slots having a longitudinal axis;

a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion struts, the second expansion column slots having a longitudinal axis; and

5 a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis and a plurality of geometric cells, at least a portion of the plurality of geometric cells being asymmetrical geometric cells, the
10 longitudinal axis of the first expansion column slots being non-parallel to the longitudinal axis of the first tubular structure.

14. The stent of claim 13, wherein the longitudinal axis of the second expansion slots is non-parallel to the longitudinal axis of the first tubular
15 structure.

15. The stent of claim 13, wherein at least one first connecting strut connects the first expansion column to the second expansion column.

20 16. The stent of claim 13, wherein a width of a first expansion column slot of the first expansion column is different from a width of a second adjacent expansion column slot of the first expansion column.

25 17. The stent of claim 13, wherein a width of a first expansion column slot of the first expansion column has a same width of a second adjacent expansion column slot of the first expansion column.

18. The stent of claim 13, wherein a width of each first expansion column slot is the same as a width of each second expansion column slot.

30

19. The stent of claim 13, wherein a width of each first expansion column slot is different from a width of each second expansion column slot.

20. The stent of claim 13, wherein the longitudinal axis of the first expansion column slots is parallel to the longitudinal axis of the second expansion column slots.

21. The stent of claim 13, wherein the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the second expansion column slots.

22. The stent of claim 13, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is non-parallel to the longitudinal axis of the first tubular structure.

23. The stent of claim 13, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is parallel to the longitudinal axis of the first tubular structure.

24. A stent in a non-expanded state, comprising:
a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion struts, wherein the first expansion column slots having a longitudinal axis;

a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion struts, the second expansion column slots having a longitudinal axis; and

a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis and a plurality of geometric cells, at least a

portion of the plurality of geometric cells being symmetrical geometric cells, the longitudinal axis of the first expansion column slots being non-parallel to the longitudinal axis of the first tubular structure.

5 25. The stent of claim 24, wherein the longitudinal axis of the second expansion slots is non-parallel to the longitudinal axis of the first tubular structure.

10 26. The stent of claim 24, wherein at least one first connecting strut connects the first expansion column to the second expansion column.

15 27. The stent of claim 24, wherein a width of a first expansion column slot of the first expansion column is different from a width of a second adjacent expansion column slot of the first expansion column.

 28. The stent of claim 24, wherein a width of a first expansion column slot of the first expansion column has a same width of a second adjacent expansion column slot of the first expansion column.

20 29. The stent of claim 24, wherein a width of each first expansion column slot is the same as a width of each second expansion column slot.

 30. The stent of claim 24, wherein a width of each first expansion column slot is different from a width of each second expansion column slot.

25 31. The stent of claim 24, wherein the longitudinal axis of the first expansion column slots is parallel to the longitudinal axis of the second expansion column slots.

32. The stent of claim 24, wherein the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the second expansion column slots.

5 33. The stent of claim 24, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is non-parallel to the longitudinal axis of the first tubular structure.

10 34. The stent of claim 24, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is parallel to the longitudinal axis of the first tubular structure.

35. A stent in a non-expanded state, comprising:
a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion struts, the first expansion column slots having a longitudinal axis;
a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion struts, the second expansion column slots having a longitudinal axis;
20 a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis, the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure
25 and the longitudinal axis of the second expansion column slots is non-parallel to the longitudinal axis of the first expansion column slots.

30 36. The stent of claim 35, wherein at least one first connecting strut connects the first expansion column to the second expansion column.

37. The stent of claim 35, wherein a width of a first expansion column slot of the first expansion column is different from a width of a second adjacent expansion column slot of the first expansion column.

5 38. The stent of claim 35, wherein a width of a first expansion column slot of the first expansion column has a same width of a second adjacent expansion column slot of the first expansion column.

10 39. The stent of claim 35, wherein a width of each first expansion column slot is the same as a width of each second expansion column slot.

40. The stent of claim 35, wherein a width of each first expansion column slot is different from a width of each second expansion column slot.

15 41. The stent of claim 35, wherein the longitudinal axis of the first expansion column slots is parallel to the longitudinal axis of the second expansion column slots.

20 42. The stent of claim 35, wherein the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the second expansion column slots.

25 43. The stent of claim 35, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is non-parallel to the longitudinal axis of the first tubular structure.

30 44. The stent of claim 35, wherein a longitudinal axis of the first connecting struts of the first connecting strut column is parallel to the longitudinal axis of the first tubular structure.

45. A stent assembly, comprising:

a balloon; and
an unexpanded stent mounted at an exterior of the balloon, the stent
including,

5 a first expansion column including a plurality of first expansion column
slots formed of a plurality of first expansion struts, the first expansion
column slots having a longitudinal axis;

a second expansion column including a plurality of second expansion
column slots formed of a plurality of second expansion struts, the second
expansion column slots having a longitudinal axis;

10 a first connecting strut column formed of a plurality of first connecting
struts, the first connecting strut column coupling the first expansion column to
the second expansion column, wherein the first expansion column, the second
expansion column and the first connecting strut column form a first tubular
structure with a longitudinal axis that is non-parallel to the longitudinal axis of
15 the first expansion column slots prior to the stent being mounted on the balloon.

46. The stent assembly of claim 45, wherein the longitudinal axis of
the second expansion slots is non-parallel to the longitudinal axis of the first
tubular structure.

20 47. The stent assembly of claim 45, wherein at least one first
connecting strut connects the first expansion column to the second expansion
column.

25 48. The stent assembly of claim 45, wherein prior to mounting the
stent on the balloon a width of a first expansion column slot of the first
expansion column is different from a width of a second adjacent expansion
column slot of the first expansion column.

30 49. The stent assembly of claim 45, wherein prior to mounting the
stent on the balloon a width of a first expansion column slot of the first

expansion column has a same width of a second adjacent expansion column slot of the first expansion column.

5 50. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon a width of each first expansion column slot is the same as a width of each second expansion column slot.

10 51. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon a width of each first expansion column slot is different from a width of each second expansion column slot.

15 52. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon the longitudinal axis of the first expansion column slots is parallel to the longitudinal axis of the second expansion column slots.

 53. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the second expansion column slots.

20 54. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon a longitudinal axis of the first connecting strut column is non-parallel to the longitudinal axis of the first tubular structure.

25 55. The stent assembly of claim 45, wherein prior to mounting the stent on the balloon a longitudinal axis of the first connecting strut column is parallel to the longitudinal axis of the first tubular structure.

30 56. The stent assembly of claim 45, wherein the balloon has a tapered geometry in an expanded state.

57. The stent assembly of claim 45, wherein the stent has a tapered diameter in an expanded state.
58. The stent assembly of claim 45, wherein the stent has a tapered geometry extending from a proximal end to a distal end in an expanded state.
59. The stent assembly of claim 45, wherein the balloon is curved extending from a proximal end and a distal end in an expanded state.
60. The stent assembly of claim 45, wherein the balloon is tapered in an expanded state and the stent has a non-tapered geometry in an expanded state.
61. The stent assembly of claim 45, wherein the balloon and the stent are both tapered in expanded state.
62. The stent assembly of claim 45, wherein the stent is non-tapered in an expanded state.
63. The stent assembly of claim 45, wherein the balloon is tapered and curved and the stent is non-tapered in an expanded state.
64. The stent assembly of claim 45, wherein the balloon is tapered and curved and stent is tapered in an expanded state.
65. A stent in a non-expanded state, comprising:
a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion struts, the first expansion column slots having a longitudinal axis;

a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion struts, the second expansion column slots having a longitudinal axis;

5 a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis, and the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure;

10 a third expansion column including a plurality of third expansion column slots formed of a plurality of third expansion struts, the third expansion column slots having a longitudinal axis;

a second connecting strut column formed of a plurality of second connecting struts, the second connecting strut column coupling the second expansion column to the third expansion column, wherein the second expansion column, the third expansion column and the second connecting strut column form a second tubular structure with a longitudinal axis, the longitudinal axis of the second expansion column slots being non-parallel to the longitudinal axis of the second tubular structure and the longitudinal axis of the second expansion column slots is non-parallel to the longitudinal axis of the first expansion column slots and the third expansion column slots.

25 66. The stent of claim 65, wherein the first tubular structure is formed of first closed cells, and the second tubular structure is formed of second closed cells.

67. The stent of claim 66 wherein the first and second closed cells are asymmetric cells.

30 68. The stent of claim 66, wherein first closed cells are non-mirror images of second closed cells.

69. The stent of claim 65, wherein the plurality of first and second connecting struts each have a stair-step configuration.

70. A stent in a non-expanded state, comprising:

a first expansion column including a plurality of first expansion column slots formed of a plurality of first expansion column strut pairs, the first expansion column slots having a longitudinal axis;

5 a second expansion column including a plurality of second expansion column slots formed of a plurality of second expansion column strut pairs, the second expansion column slots having a longitudinal axis;

a first connecting strut column formed of a plurality of first connecting struts, the first connecting strut column coupling the first expansion column to the second expansion column, wherein the first expansion column, the second expansion column and the first connecting strut column form a first tubular structure with a longitudinal axis, and the longitudinal axis of the first expansion column slots is non-parallel to the longitudinal axis of the first tubular structure;

15 a third expansion column including a plurality of third expansion column slots formed of a plurality of third expansion strut pairs, the third expansion column slots having a longitudinal axis;

a second connecting strut column formed of a plurality of second connect struts, the second connecting strut column coupling the second expansion column to the third expansion column, wherein the second expansion column, the third expansion column and the second connecting strut column form a second tubular structure with a longitudinal axis, the longitudinal axis of the second expansion column slots being non-parallel to the longitudinal axis of the second tubular structure and the longitudinal axis of the second expansion column slots is non-parallel to the longitudinal axis of the first expansion column slots and the third expansion column slots, wherein the first expansion column strut pairs are formed of parallel first expansion column strut pairs, the second expansion column strut pairs are formed of non-parallel second expansion column struts and the third expansion column strut pairs are formed of parallel third expansion column struts.

30 71. The stent of claim 68, wherein the first tubular structure is formed of first closed cells, and the second tubular structure is formed of second closed cells.

72. The stent of claim 69, wherein the first and second closed cells are asymmetric cells.

5 73. The stent of claim 69, wherein first closed cells have different second closed cells have different geometric shapes.

74. The stent of claim 68, wherein the plurality of first and second connecting struts each have a stair-step configuration.

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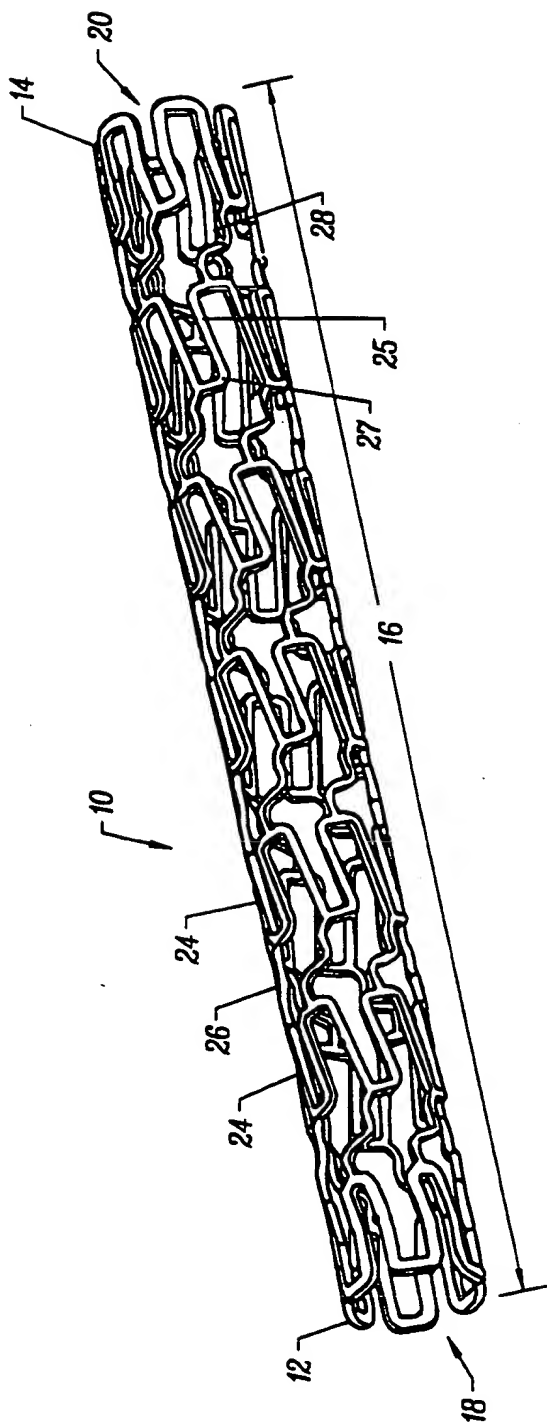


FIG. 1

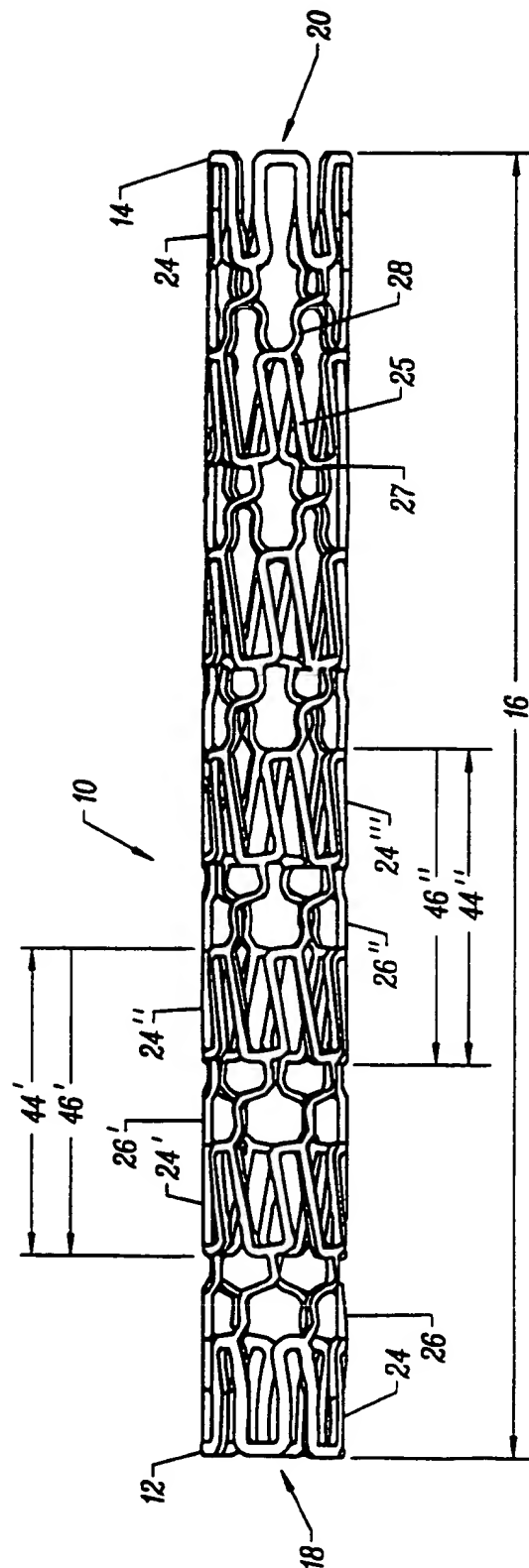


FIG. 2

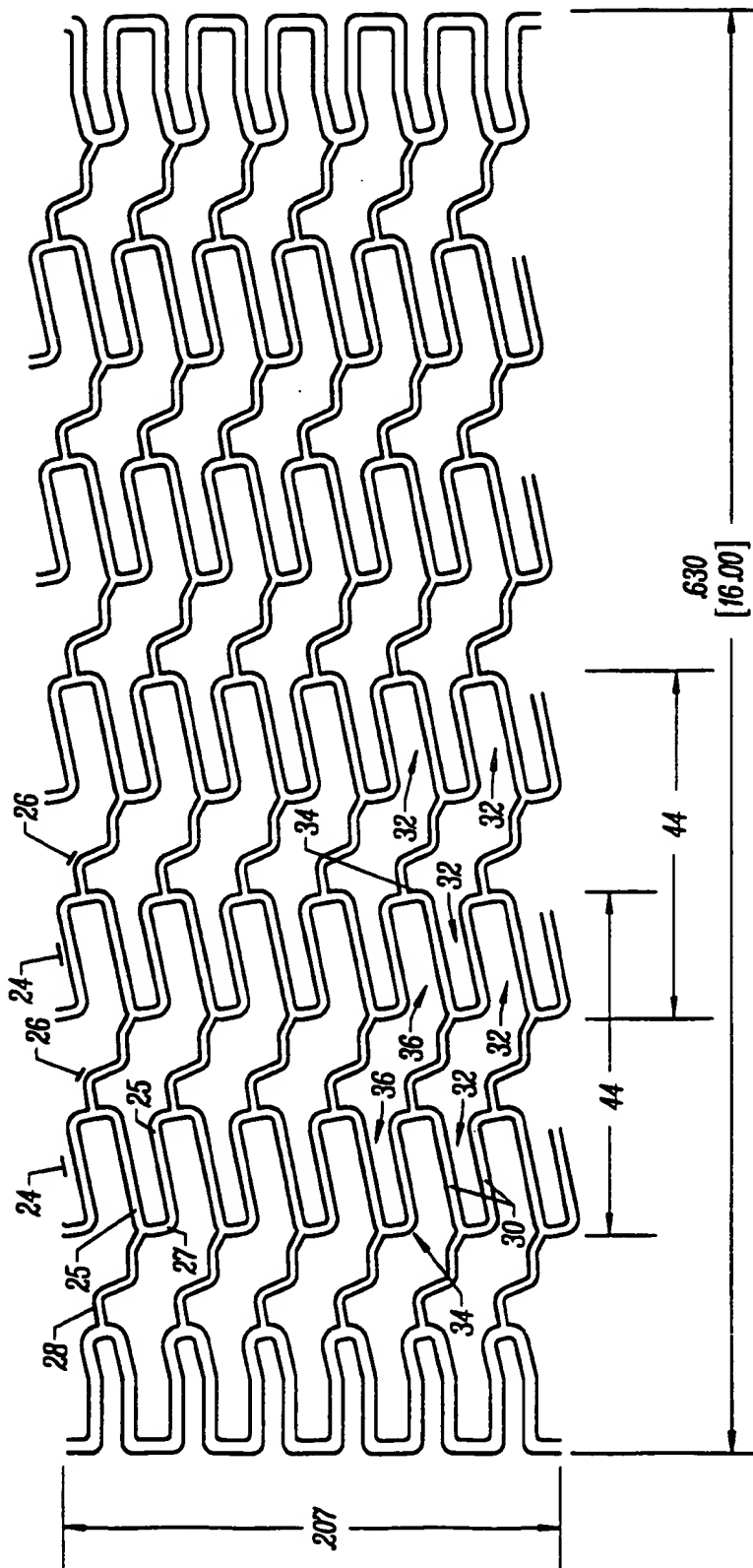
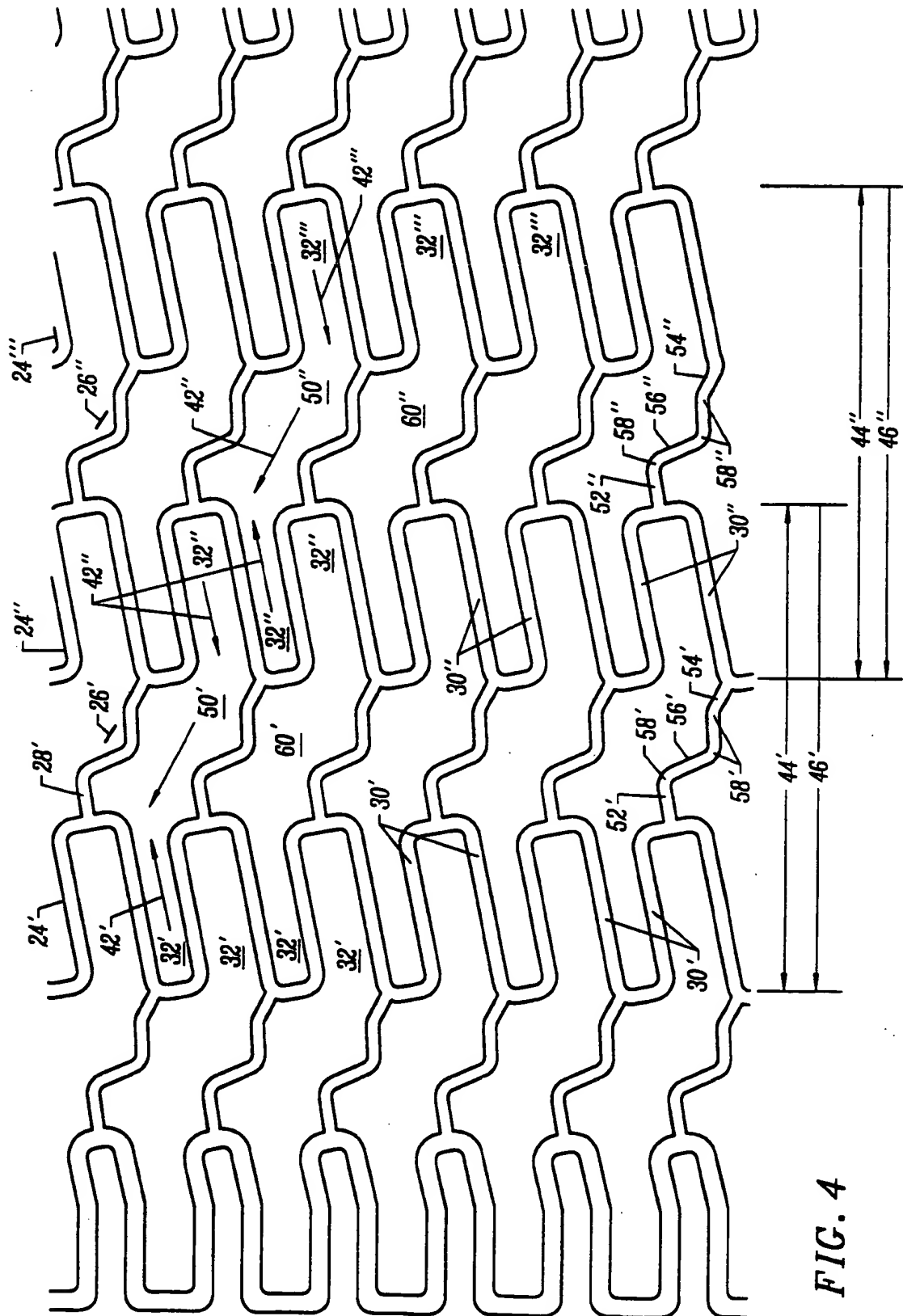


FIG. 3



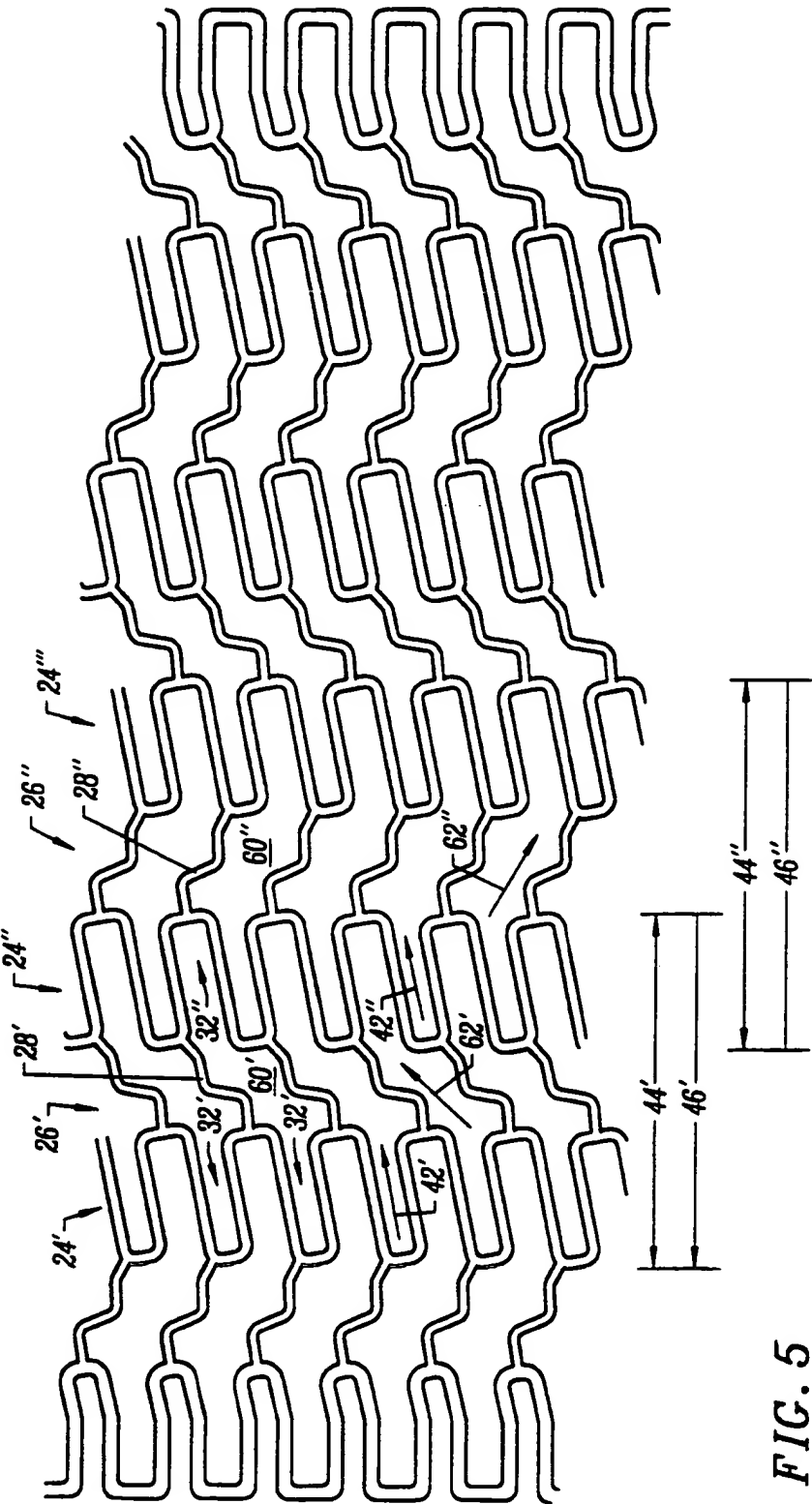
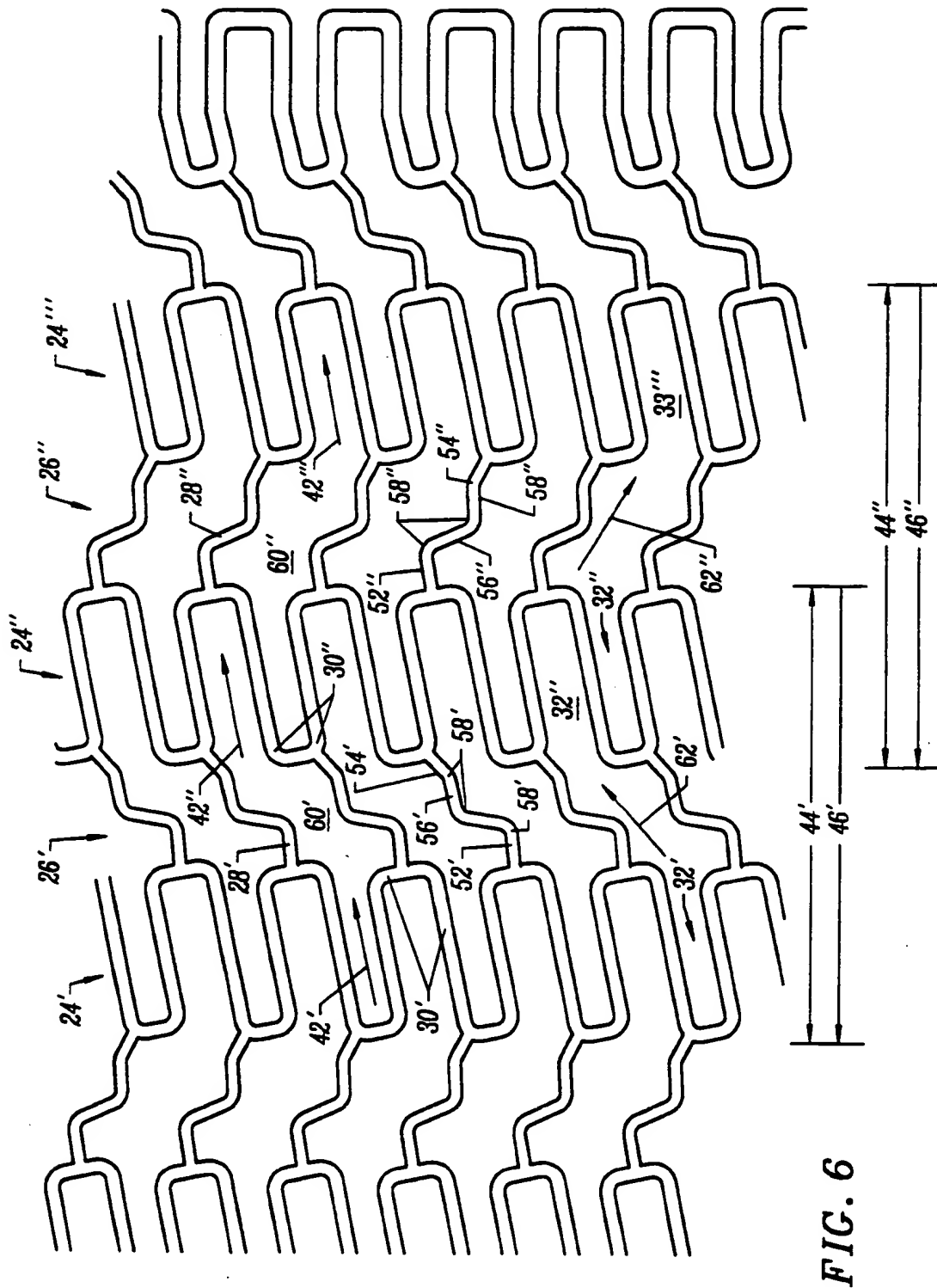


FIG. 5



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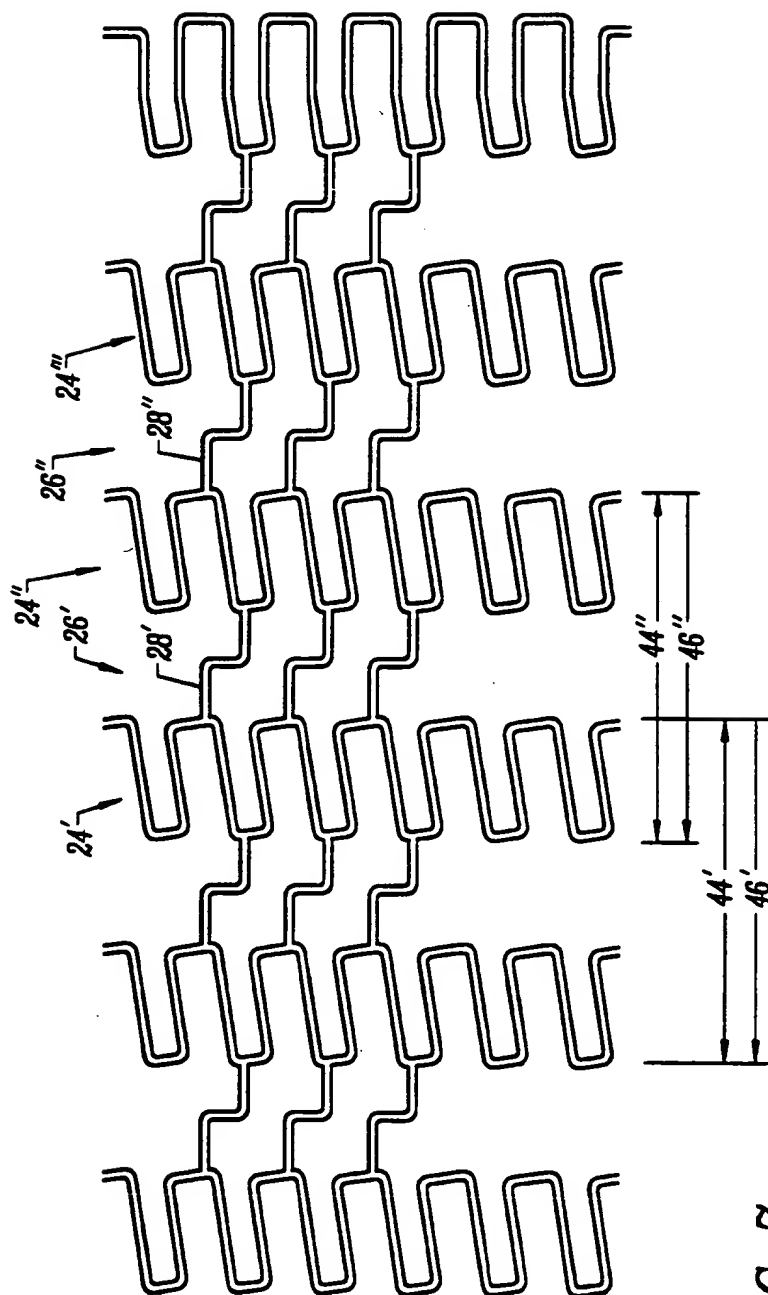


FIG. 7

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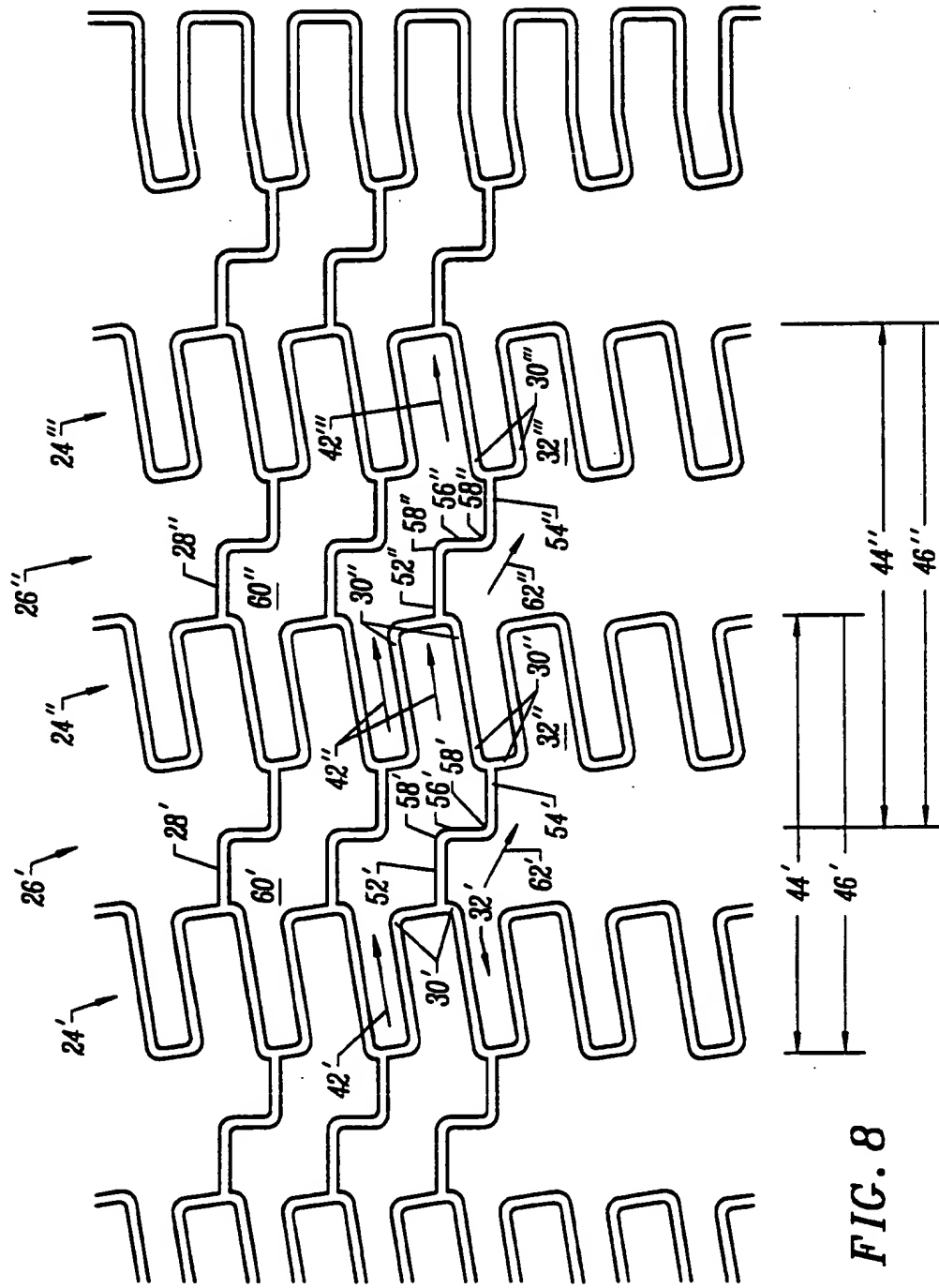


FIG. 8

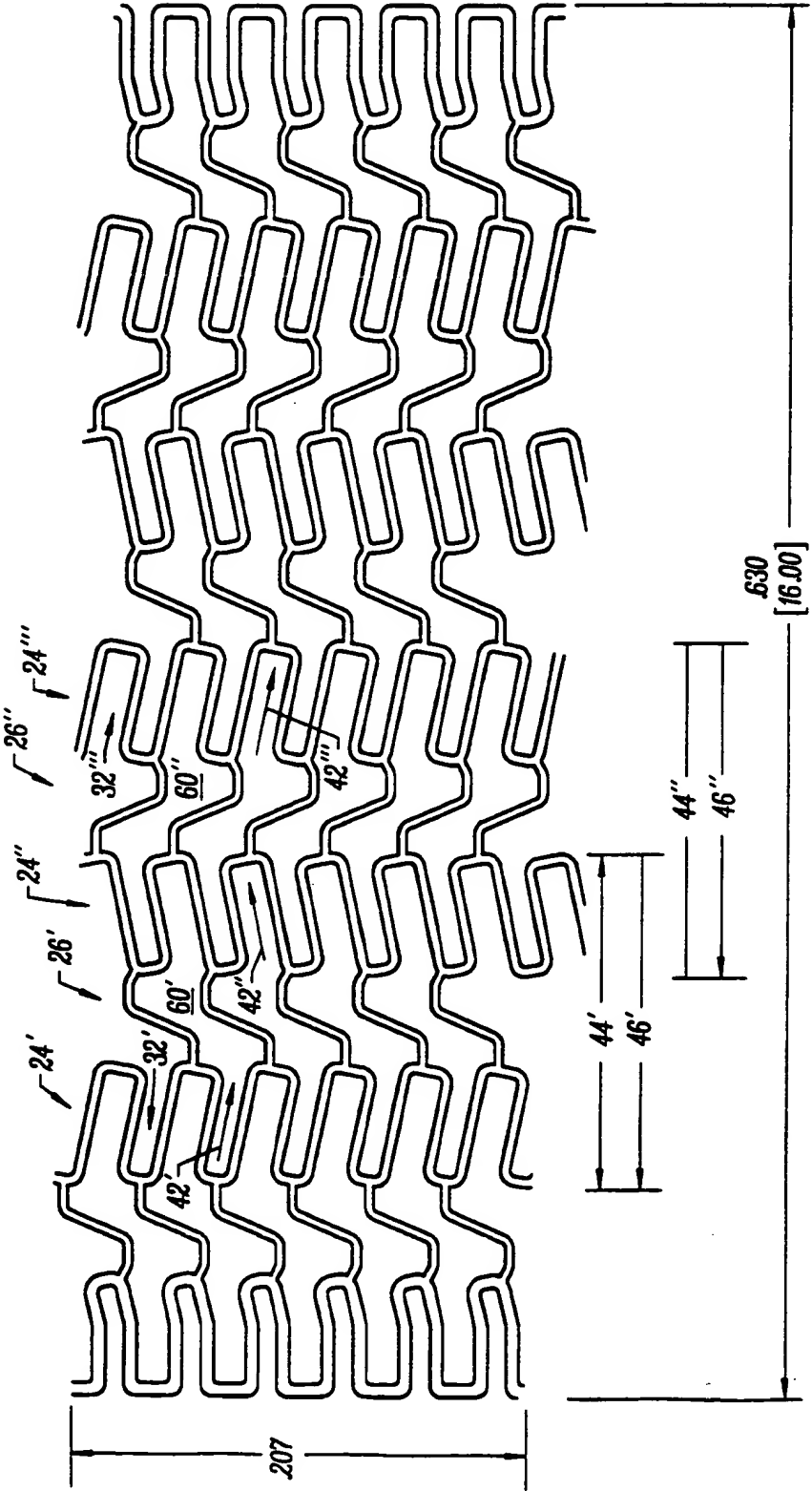
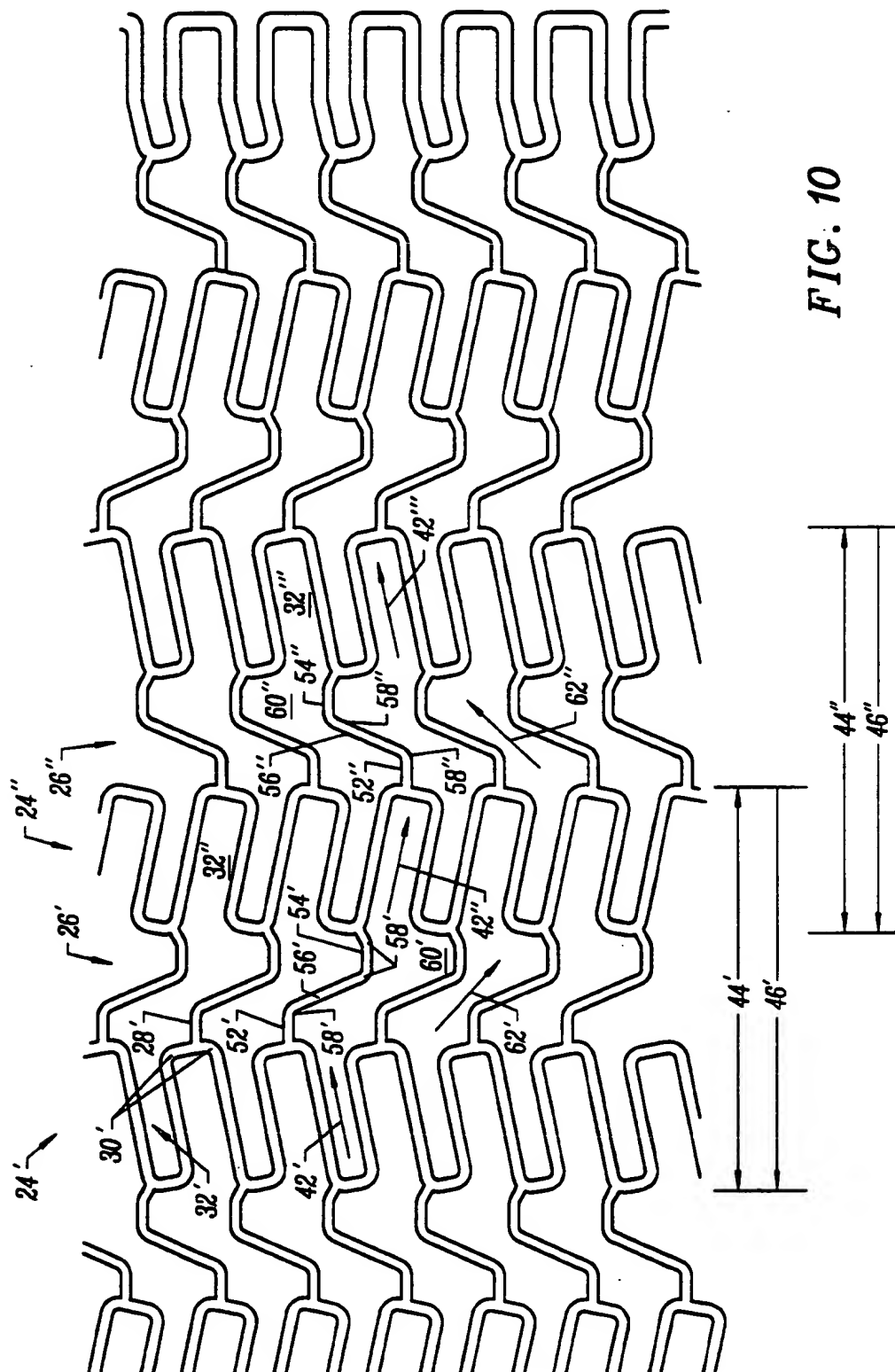


FIG. 9

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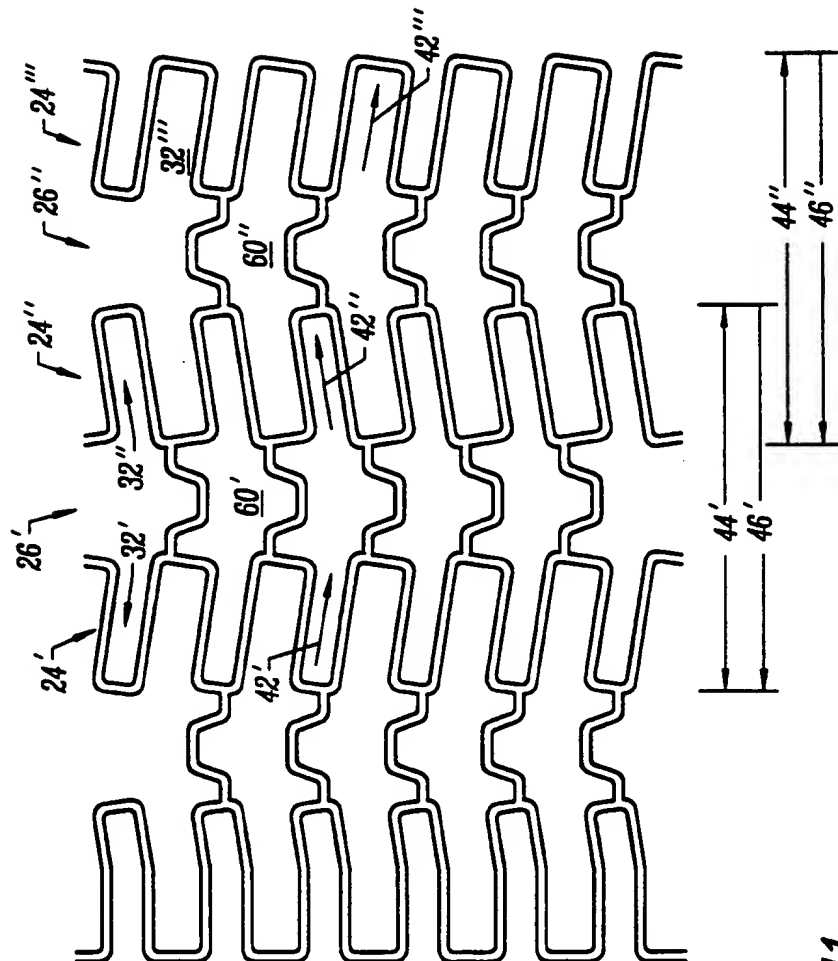


FIG. 11

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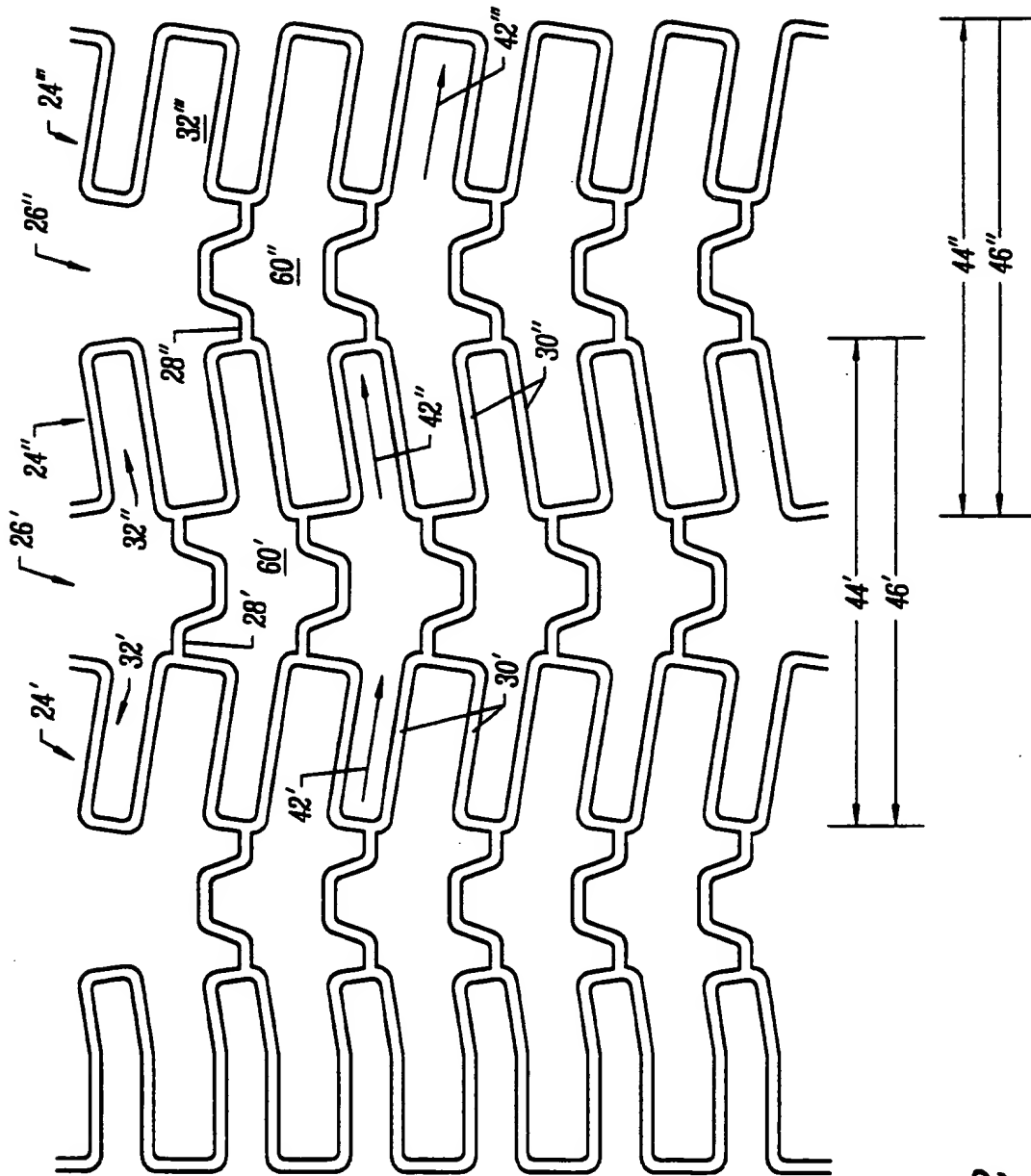


FIG. 12

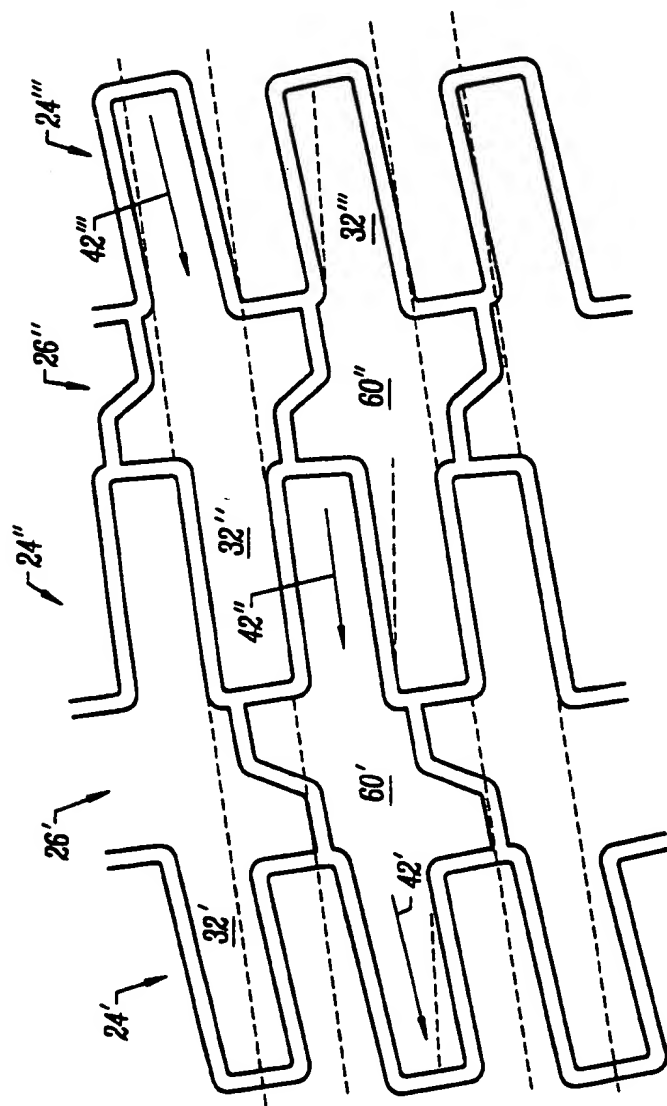


FIG. 13

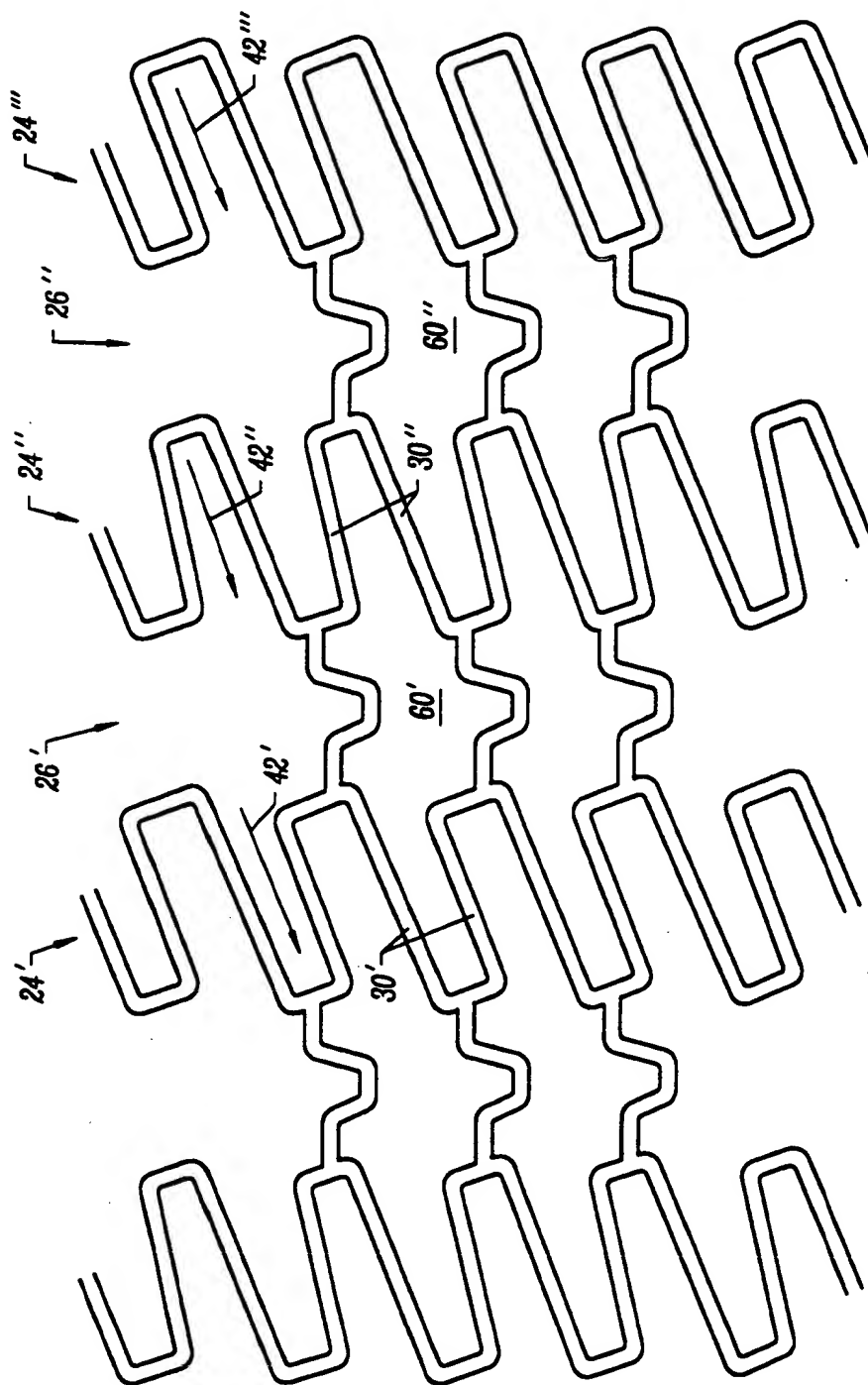


FIG. 14

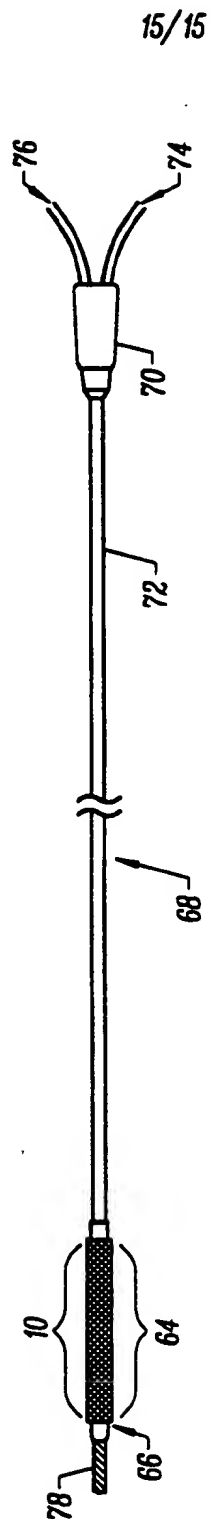


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/15531

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	EP 0 824 902 A (KANESAKA NOZOMU ; TASHJI GEORGE A (US)) 25 February 1998	1, 2, 4-6, 10, 12-18, 21, 23-29, 32, 34-37, 42, 44-46, 48-50, 54, 55, 65-68
Y	see figure 1 see column 4, line 9 - line 39 see column 5, line 37 - line 44 -/-	11, 19, 20, 22, 30, 31, 33, 40, 43, 70-74

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 November 1998

Date of mailing of the international search report

07/12/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/15531

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DE 297 02 671 U (JOMED IMPLANTATE GMBH) 10 April 1997</p>	<p>1,2,4,5, 7,8,10, 12,35, 36,38, 39,42, 44-46, 48-50, 54,55, 65-69 19,30, 40,74</p>
Y	<p>see figures 5,7</p> <p>see page 10, line 19 - line 34</p>	
P,X	<p>US 5 776 161 A (GLOBERMAN OREN) 7 July 1998</p>	<p>1-4,6,7, 9,12,35, 36,38, 39,41, 44-46, 48-50, 54,55 20,31</p>
Y	<p>see figures 14,16</p> <p>see column 7, line 14 - line 31</p>	
Y	<p>US 5 102 417 A (PALMAZ JULIO C) 7 April 1992 cited in the application see figure 7 see column 11, line 35 - column 12, line 33 see claim 30</p>	<p>11,22, 33,43</p>
P,Y	<p>WO 97 40783 A (JANG G DAVID) 6 November 1997 see figure 1A see page 8, line 23 - page 12, line 18</p>	<p>70-73</p>

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